APR 2 8 2014

5.0 510(k) SUMMARY

5.1 Sponsor Information[1]

Company Information: Innovacyn, Inc.
3546 N. Riverside Ave.
Rialto, CA 92377

Contact Information: Dr. Fred Ma M.D., Ph.D.
Chief Medical Officer
909-349-3370, Ext. 375
fma@innovacyn.com

Date of Preparation: November 13, 2013

Date of Revision: April 3, 2014

5.2 Device Information

Common Name: Wound Cleanser

Trade Name: Puracyn Plus™ Skin and Wound Care

Classification Name: Dressing, wound, drug

Device Class: Unclassified

Device Code: FRO

Classification Panel: General and Plastic Surgery

5.3 Identification of Legally Marketed Device for Substantial Equivalence Comparison:

K093697: Vashe® Wound Therapy Solution (OTC use) manufactured by PuriCore, Inc.

K123072: Vashe® Wound Therapy Solution (Professional use) manufactured by PuriCore, Inc.

K113693: Nixall™ Wound and Skin Care (OTC and Professional use) manufactured by Seriously Clean Ltd.

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[1] Innovacyn has contracted with Aquaox Inc. and its subsidiary, Aquaox Industries, for the exclusive use of equipment and technology that has been developed by Aquaox Inc. for the manufacture of hypochlorous acid solutions such as those used in Puracyn Plus™ Skin and Wound Care (which is referred in the Aquaox documentation as AX250).

5.4 Device Description

Puracyn Plus™ Skin and Wound Care is a clear hypotonic solution topically applied to skin and wound areas. The subject device is a wound management and cleansing solution that is intended for cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings (e.g. gauze). The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris. Puracyn Plus™ Skin and Wound Care will be supplied in food grade 4 oz. plastic PET bottles with spray inserts and caps.

5.5 Intended Use

Puracyn Plus™ Skin and Wound Care is intended for over-the-counter use and professional use as follows:

OTC: Puracyn Plus™ Skin and Wound Care is intended for the OTC use of the management of minor skin wounds including minor lacerations, minor abrasions, minor irritations, minor cuts, minor burns and intact skin, in addition to moistening and lubricating absorbent wound dressings.

Professional Use: Puracyn Plus™ Skin and Wound Care is intended for use by healthcare professionals for cleansing, irrigating, moistening, and debriding to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wounds such as 1st and 2nd degree burns, stage I – IV pressure ulcers, diabetic ulcers, stasis ulcers, abrasions and minor skin irritations, post-surgical wounds, grafted and donor sites, in addition to moistening and lubricating absorbent wound dressings.

These indications are similar to the predicate devices (Vashe® Wound Therapy Solution and Nixall™ Wound and Skin Care).

5.6 Device Technological Characteristics

Puracyn Plus™ Skin and Wound Care is a clear hypotonic solution to aid in the removal of debris and foreign material from the application site. This is accomplished through the flow of the solution moving across the application site with or without the assistance of a suitable wound dressing. Puracyn Plus™ Skin and Wound Care solution contains a preservative that may help inhibit the growth of microorganisms within the solution. Puracyn Plus™ Skin and Wound Care is manufactured under Good Manufacturing Practices (GMP) guidelines.

5.7 Performance Testing

ISO 10993 biocompatibility testing established the safety of Puracyn Plus™ Skin and Wound Care for its intended use. The overall biocompatibility testing results warrant Puracyn Plus ™ Skin and Wound Care product as a safe to use medical device, i.e. non-cytotoxic, non-

sensitizing, non-irritating, and non-toxic. The results of stability testing have demonstrated the product is stable for at least 11 months when stored at 25°C/60%RH±2% Stability Conditions.

5.8 Substantial Equivalence

Puracyn Plus™ Skin and Wound Care is substantially equivalent to the cited predicate devices based on similarity of use indications, functionality, chemical and physical characteristics, antimicrobial activity, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609

Silver Spring, MD 20993-0002

April 28, 2014

Innovacyn Incorporated
Fred Ma, M.D., Ph.D.
Chief Medical Officer
3546 North Riverside Avenue
Rialto, California 92377

Re: K133542
Trade/Device Name: Puracyn Plus™ Skin and Wound Care
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 3, 2014
Received: April 4, 2014

Dear Dr. Ma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133542

Device Name
Puracyn Plus™ Skin and Wound Care

Indications for Use *(Describe)*

OTC: Puracyn PlusTM Skin and Wound Care is intended for the OTC use of the management of minor skin wounds including minor lacerations, minor abrasions, minor irritations, minor cuts, minor burns and intact skin, in addition to moistening and lubricating absorbent wound dressings.

Professional Use: Puracyn PlusTM Skin and Wound Care is intended for use by healthcare professionals for cleansing, irrigating, moistening, and debriding to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wounds such as 1st and 2nd degree burns, stage I – IV pressure ulcers, diabetic ulcers, stasis ulcers, abrasions and minor skin irritations, post-surgical wounds, grafted and donor sites, in addition to moistening and lubricating absorbent wound dressings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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